

REMARKS

Entry of the above amendments and reconsideration of this application are respectfully requested. Upon entry of the amendments, this application will contain claims 1-19, 42-49, 51-72 pending and under consideration. Each of the objections and/or rejections to these claims set forth in the Office Action are addressed in sequence below. It is believed that each such objection or rejection is overcome, and thus reconsideration and allowance of this application are requested.

Claims 1-19, 42, and 56-59 stand rejected under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In support of this rejection, the Examiner has asserted that the recitation of “at least about” renders the claims indefinite. To respond to this rejection, the claims have been amended to change “at least about” to “at least”. This amendment is made in hopes of expediting the current prosecution, and is without prejudice. Withdrawal of this rejection is solicited. The Action also noted a need to delete the identification of claim “44” from claim 46. This amendment has been shown in the above changes (with double strikethrough for clarity through the number 4’s).

Claims 42-43, 45-48, 51-53, and 60-62 stand rejected under 35 USC § 102(b) as being anticipated by Chu et al., U.S. Patent No. 4,888,366; wherein claims 42, 48, 51-53, and 61-62 remain rejected under 35 USC 102(b) as being anticipated by Chu et al. Because the Chu et al. patent fails to teach each and every element of the rejected claims, this rejection is respectfully traversed.

Of this group of rejected claims, all of the claims except claims 43, 45-47 and 51-53 require that require a composition that is “three dimensionally stable but flexible”. To the contrary, the prosthesis devices of Chu et al. are specifically taught as “being rigid with a compressive strength of at least twenty Newtons per square centimeter” (see column 2, lines 46-51). Here and in other locations, Chu et al. teaches directly away from

compositions with the claimed properties (see e.g. also Col. 2, line 30, describing a “rigid preparation”).

Further, with regard to the remaining claims that have been subjected to this rejection, claims 43, 45-47 and 51-53, these each require a “sponge matrix comprising lyophilized collagen”, in combination with the required, advantageously high levels of mineral relative to collagen (1-3% collagen versus 97-99% mineral). Chu et al. also fails to teach the combination of claimed features, and in fact teaches against it (see, e.g., Col. 9, lines 24-26, “Drying by lyophilization at the final step produces a spongy product nonconforming with regard to strength and homogeneity”; and examples 2 and 5 in which a lyophilized product was made and compared (unfavorably) with the rigid products taught by Chu et al.).

For the foregoing, reasons, withdrawal of the rejection of claims 42-43, 45-48, 51-53, and 60-62 as being anticipated by Chu et al. is respectfully solicited.

Claims 67-71 stand rejected under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Chu et al., U.S. Patent No. 4,888,366. This rejection is respectfully traversed to the extent maintained against any remaining claim.

Claims 67-71 as amended each require one or both of “lyophilized collagen” or a “three-dimensionally stable but flexible” matrix. Chu et al. neither anticipates nor renders obvious the claimed combinations of features, for the reasons discussed in more detail above. Again, Chu et al. not only fails to teach the combinations of the claimed features, but expressly teaches directly against them. Chu et al. expressly teaches that the processing of materials used in the implant can have an effect on the implant properties, and specifically motivates that the materials be processed in a way to obtain a rigid device. With that being the case, it is submitted that when properly considered, the Chu et al. reference cannot be found to anticipate or render obvious these or any other remaining claims. Withdrawal of this rejection is therefore solicited.

Claims 43, 45-47 and 57-60 stand rejected under 35 USC 102(b) as being anticipated by Smestad et al., U.S. Patent No. 5,123,925. This rejection is respectfully traversed.

As to claims 43, 45-47 and 57-59, these require a “sponge matrix formed of lyophilized collagen” in combination with the claimed, very high ratio of mineral to collagen. Smestad et al. fails to teach this claimed combination of elements. Instead, Smestad et al. teaches (and appears to favor, for providing compression strength) mostly preparations that involve drying processes other than lyophilization, in particular these are heated air drying processes, similar to Chu et al.. Where lyophilization processing is taught, the claimed high level of mineral to collagen is not taught (see e.g. Example 1(D)).

As to claim 60, this claim requires not only the very high mineral to collagen ration (1-3% collagen, 97-99% mineral, 1-3% collagen, but also that the device be “three-dimensionally stable but flexible”. Smestad et al. also fail to teach this combination of features.

In view of the foregoing, it is submitted that the rejection over Smestad et al. is overcome, and its withdrawal is solicited.

Claims 1-8, 11-14, 18-19, 56-59 and 65-66 stand rejected under 35 USC 103(a) as being unpatentable over Chu et al., U.S. Patent No. 4,888,366.

As discussed above, each of these claims includes not only the high mineral/collagen ratios claimed, but also the feature of a “three-dimensionally stable but flexible” material. Chu et al. does not teach, suggest, or motivate the claimed combinations of features, and in fact teaches directly against them. It is therefore submitted that the above claims are patentably distinct from the Chu et al. reference, and withdrawal of this rejection is solicited.

Finally, a number of groups of claims stand rejected as being unpatentable over Chu et al. in view of secondary references under 35 U.S.C. 103(a). However, each of the rejected claims depends upon a claim that includes a lyophilized feature or a “three-

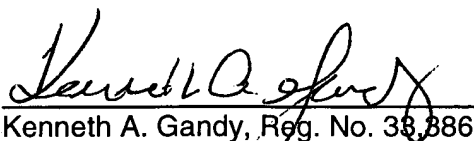
dimensionally stable but flexible" feature in combination with the other claimed elements.

None of the secondary references does or can negate the teachings away of the Chu et al. reference noted above. Accordingly, it is submitted that the remainder of the rejections are also overcome, and their withdrawal is earnestly solicited.

For the foregoing reasons, it is submitted that this application is in condition for allowance. Prompt action to that end is solicited.

Respectfully submitted,

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